Editor claims drug companies have a "parasitic" relationship with journals

The relationship between medical journals and the drug industry is "somewhere between symbiotic and parasitic," according to the editor of the *Lancet*, Richard Horton. But at the moment it has swung too much towards the parasitic, he told the House of Commons select committee on health last month in his oral evidence on the role of the industry.

He outlined some of the financial incentives that could, potentially, influence a commercially run medical journal to publish a paper. Many of the formal research papers in the *Lancet* are reprinted and bought in bulk by drug companies, which use them for marketing purposes, he explained.

Dr Horton cited the example of a recently submitted paper on cyclo-oxygenase-2 inhibitors. When the journal raised questions with the authors over the paper, the drug company sponsoring the research telephoned Dr Horton, asking him to "stop being so critical." The company told him, "If you carry on like this we are going to pull the paper, and that means no income for the journal."

Lynn Eaton *London*

The transcript of the oral evidence is available at www.publications.parliament.uk/pa/cm/cmhealth.htm

New US "abortion non-discrimination act" faces legal challenges

The state of California and the National Family Planning and Reproductive Health Association are challenging the "abortion non-discrimination amendment" that a Congressman has attached to a federal funding bill.

The amendment allows doctors, hospitals, and insurance companies to refuse to provide, pay for, or give referrals for abortions—without penalty. It conflicts with an existing law, called Title X, that requires many health providers to inform pregnant women of all options, including abortion.

If a state tries to enforce state laws safeguarding a woman's right to abortion information and services, it might lose billions of dollars in federal funding.

California's state attorney general, Bill Lockyer, will file a lawsuit to block the amendment next week. He said the amendment would deny all funds to California provided by the federal funding bill if the state enforced state laws to safeguard women's constitutional rights to abortion.

Janice Hopkins Tanne *New York*

Government to review doctors' revalidation system

The General Medical Council has postponed the introduction of its new system for assessing doctors' fitness to practise after the government asked to review the scheme because of criticisms of it in the fifth report of the Shipman inquiry.

The council's new scheme of revalidation will be shelved until the review is complete, which will not be until after the scheme was due to be launched in April 2005. The review, which is being led by Professor Liam Donaldson, the chief medical officer, will audit the proposed arrangements in detail. A statement from the Department of Health suggests that the proposed appraisal system may need to be strengthened to protect both patients and doctors.

The health minister Lord Warner said: "It would be unfair to doctors and confusing for patients to start the new revalidation scheme on one basis and then to make changes after considering Dame Janet's report. It would not be appropriate to ask parliament to consider the legislation needed to implement the changes proposed for April 2005 with such a level of uncertainty. That is why the changes cannot proceed as planned." (See p 10.)

Zosia Kmietowicz *London*

Warnings issued over COX 2 inhibitors in US and UK

Scott Gottlieb *New York*

Warnings were issued last month about two COX 2 (cyclo-oxygenase-2) inhibitors because of fears that they might increase the risk of cardiovascular events, including heart attacks and strokes.

Celecoxib (Celebrex) showed an increased risk of cardiovascular events in a long term study (sponsored by the US National Cancer Institutes) that looked at use of the drug for prevention of colon cancer.

Patients in the five year trial taking 400 mg/day or 800 mg/day of celecoxib had, respectively, a 2.5-fold and 3.4-fold increased risk of a major cardiovascular event compared with placebo. The Food and Drug Administration and the National Cancer Institutes announced jointly that 2.2% of patients given 400 mg/day and 3% of patients given 800 mg/day had a cardiovascular event, compared with 0.9% of patients taking placebo.

The trial involved 2400 patients, who took the drug for an average of 33 months. It has now been suspended.

Pfizer said that results from a long term, company sponsored trial of celecoxib in patients with cancer—known as the PreSAP study—had shown no greater risk of cardiovascular events in patients receiving celecoxib than in those receiving placebo. A third study, which has enrolled about 2000 patients at high risk of Alzheimer's disease, was reviewed by a data monitoring board on 10 December and allowed to continue with no changes.

Pfizer said that for now it would not withdraw celecoxib from the market. The FDA said that "all regulatory options" were still possible. In the meantime, the FDA's commissioner, Dr Lester Crawford, said that the FDA is advising physicians to consider alternatives to celecoxib and patients to consult their doctors.

Professor Gordon Duff, chairman of the British Committee on the Safety of Medicines, has sent an urgent email to all doctors in the United Kingdom, saying that any patients with established ischaemic heart disease or cerebrovascular disease who are being treated with any COX 2 inhibitor should be switched to alternative (non-COX 2 selective) treatments as soon as is convenient.

A letter to the *New England Journal of Medicine* released on the journal's website last month said that another COX 2 inhibitor, valdecoxib (Bextra), carries the same risks of increased cardiovascular outcomes of stroke and myocardial infarction as celecoxib and rofecoxib (Vioxx) and should be taken off the market. Rofecoxib was withdrawn from the market by its manufacturer, Merck, in September (*BMJ* 2004;329:816).

"To protect the safety of the public, we write to recommend that clinicians stop prescribing valdecoxib except in extraordinary circumstances.

"This recommendation is based on the long delay between the initial evidence of the cardiotoxicity of rofecoxib and its withdrawal, recent studies demonstrating the cardiotoxicity of valdecoxib in high-risk patients, the availability of other therapies not currently known to have cardiovascular risks, and the lack of compelling evidence of countervailing benefits," the authors wrote (*New England Journal of Medicine* 2004;351:2767). □

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Patients taking a high dose of celecoxib in a recent trial were three times more likely to have a cardiovascular event than those taking placebo